MAR 16 2005

K042899

510(k) Summary

Sponsor:

SYNTHES (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes (USA) Reamer Irrigator Aspirator (RIA) System

Classification: Class II, 21 CFR §888.4540, 888.1100
Orthopedic manual surgical instrument
Arthroscope and Accessories

Predicate Device: Synthes RIA System
Spine-Tech Bone Harvester

Device Description: Synthes RIA System is a flexible reaming device that consists of a series of disposable tube assemblies, disposable reamer heads, tube assemblies, drive shaft seals and reusable drive shafts. The device is designed for expedited reaming of the medullary canal in preparation for internal fixation. The RIA System is also designed to harvest bone and bone marrow. The free-rotating reamer head attaches to the distal end of the tube assembly. Ports in the manifold of the tube assembly allow simultaneous irrigation and aspiration through the tube assembly during the reaming process. Irrigating fluid is passed through the cannula of the drive shaft and reamer head and aspiration is drawn through ports of the retainer and aspiration tube. The RIA System is available in various lengths and diameters.

Intended Use: Synthes RIA System is intended to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis; and to harvest finely morselized autogenous bone and bone marrow for any surgical procedure requiring bone graft to facilitate fusion and/or fill bone defects. These procedures include spinal fusion, joint arthrodesis, total joint replacement, fracture repair, nonunion, maxillofacial reconstruction, and tumor removal.

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes RIA System, is substantially equivalent* to other legally marketed devices.

* The term "substantially equivalent" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A

determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matter. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K042899
Trade/Device Name: Synthes (USA) Reamer Irrigator Aspirator (RIA) System-Expanded Indications
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HTO and NBH
Dated: March 4, 2005
Received: March 7, 2005

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042899

Device Name: Synthes (USA) Reamer Irrigator Aspirator (RIA) System – Expanded Indications

Indications: Synthes RIA System is intended to clear the medullary canal of bone marrow and debris and to effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis; and to harvest finely morselized autogenous bone and bone marrow for any surgical procedure requiring bone graft to facilitate fusion and/or fill bone defects. These procedures include spinal fusion, joint arthrodesis, total joint replacement, fracture repair, nonunion, maxillofacial reconstruction, and tumor removal.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(K) Number K042899